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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,532	12/21/2001	Szu-Min Lin	ASP-54	5937
27777	7590	10/19/2005	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			CHORBAJI, MONZER R	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/029,532	Applicant(s) LIN, SZU-MIN	
	Examiner MONZER R. CHORBAJI	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 15-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This final rejection is in response to the communication received on 07/27/2005

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-3, 6 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langford (U.S.P.N. 5,443,801) in view of Younkes (WO 98/03211).

With respect to claim 1, the Langford reference teaches a sterilization system that includes the following: a sealed sterilization container (figure 18, 180) for containing items to be sterilized (col.23, lines 31-32) such that the container has an inlet and an outlet ports (col.23, line 29), a source of sterilizing fluid attachable to and detachable from the inlet and the outlet ports (col.23, lines 50-52 and lines 59-64), and the container is sealed from microorganism ingress while disconnected from the source to maintain sterility of the items therein (col.23, lines 59-64). The Langford reference fails

to disclose the use of a passive microorganism impermeable closure; however, the Younkes reference, which is in the art of designing and maintaining medical items in sterile conditions, teaches the use a passive microorganism impermeable closure (page 12, lines 29-33 and figure 8, 270). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Langford system by substituting one closure means for another as taught by the Younkes reference since such a substitution results in the use of partial hermetic seal that insures sterility and allows air to be expelled to the outside (page 13, lines 1-5).

With respect to claims 3, 6 and 19, the Langford reference teaches a valve biased into a closed position (col.23, lines 60-64) and a pressure differential to create flow between the inlet and the outlet ports of the container (col.23, lines 44-45 such that the pump creates a pressure differential for the sterilant flow to occur).

With respect to claim 2, the Younkes reference teaches the use of a vapor permeable, microorganism impermeable cover (page 12, lines 29-33).

4. Claims 4-5, 7, 17-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langford (U.S.P.N. 5,443,801) as applied to claims 1-2, 6, 19 and further in view of Younkes (WO 98/03211) and Koubek (U.S.P.N. 4,512,951).

With respect to claims 4-5 and 17-18, both the Langford reference and the Younkes reference fail to disclose using vaporous hydrogen peroxide; however, the Koubek reference, which is in the art of sterilization, teaches using vaporous hydrogen peroxide (col.3, lines 24-25). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Langford system by

substituting one conventional sterilant for another as taught by the Koubek reference since such a substitution results in increasing the killing rate activity of the sterilant by creating a liquid hydrogen peroxide condensate in the presence of a vacuum (col.2, lines 9-15).

With respect to claims 7 and 20, the Langford reference uses a pump for moving the sterilant into and out of the container (col.23, lines 44-45), but fails to teach the use of a fan for creating a sterilant motion. With respect to claims 7 and 20, the Younkes reference fails to teach the use of a fan; however, the Koubek reference, which is in the art of sterilizing medical items by using vaporous hydrogen peroxide, uses a fan (17) for distributing the sterilant. The motion of the fan creates a pressure differential between the inlet and the outlet of the sterilizer. So, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Langford system by substituting one conventional moving means for another as taught by the Koubek reference since such a substitution insures a uniform distribution of the inflowing hydrogen peroxide vapors within the container (col.3, lines 63-67).

5. Claims 8 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langford (U.S.P.N. 5,443,801) as applied to claims 1-2 and further in view of Younkes (WO 98/03211) and Sanderson (U.S.P.N. 4,754,595).

With respect to claims 8 and 21, both the Langford reference and the Younkes reference fail to teach the use of baffles; however, the Sanderson reference, which is in the art of vapor sterilization of medical items, teaches the use of baffles (figures 1-2,15). As a result, it would have been obvious to one having ordinary skill in the art at the time

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the invention was made to modify the Langford system by including baffles in the container as shown by the Sanderson reference in order to control the flow of the sterilant into and out of the container.

6. Claims 9-11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langford (U.S.P.N. 5,443,801) in view of Younkes (WO 98/03211) and further in view of Wright et al (U.S.P.N. 5,639,031).

With respect to claim 9, the Langford reference teaches a method for sterilizing medical items (col.4, lines 49-68 and col.5, lines 1-11) including the following: placing the items into a sealed container (col.23, lines 31-32), attaching a source of sterilizing fluid to the container (col.23, lines 50-52), flowing the sterilant into the container through a first port and then flowing the sterilant through the container and out through a second port (figure 18, 183A and col.23, lines 50-52), detaching the container and sealing the container the container in order to maintain sterility (col.23, lines 59-64). However, with respect to claim 9, the Langford reference fails to teach using a passive microorganism impermeable closure and returning the sterilant back to the source. The Younkes reference, which is in the art of designing and maintaining medical items in sterile conditions, teaches using a passive microorganism impermeable closure (page 12, lines 29-33 and figure 8, 270). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Langford system by substituting one closure means for another as taught by the Younkes reference since such a substitution results in the use of partial hermetic seal that insures sterility and allows air to be expelled to the outside (page 13, lines 1-5).

With respect to claim 9, the Younkes reference fails to teach the step of returning the sterilant back to the source; however, the Wright reference, which is in the art of sterilizing medical sharps, teaches the step of returning the sterilant back to the source (col.2, lines 49-52). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Langford system by including a sterilant recycling means as taught by the Wright reference since reusing the sterilant result in lowering the expense of disposing medical waste and preventing ground water pollution (col.2, lines 11-14).

With respect to claim 10, the Younkes reference seals a container having a port with a microorganism impermeable, vapor permeable material (page12, lines 29-33 and figure 8, 270).

With respect to claim 11, the Langford reference teaches an automatic closing valve (col.23, lines 59-64) that closes the container port prior to full disconnection of the container from the source of the sterilizing fluid (col.23, lines 60-61).

With respect to claim 15, the Langford reference teaches flowing the sterilant into the container through a first port and then flowing the sterilant through the container and out through a second port (figure 18, 183A and col.23, lines 50-52), but fails to teach returning the sterilant back to the source thereby resulting in a continuous flow between the source and the container. The Wright reference, which is in the art of sterilizing medical sharps, teaches the step of returning the sterilant back to the source (col.2, lines 49-52) such that a continuous flow path between the container (30) and the sterilant source is continuous. Thus, it would have been obvious to one having ordinary

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skill in the art at the time the invention was made to modify the Langford system by including a sterilant recycling means as taught by the Wright reference since reusing the sterilant result in lowering the expense of disposing medical waste and preventing ground water pollution (col.2, lines 11-14).

7. Claims 12-13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langford (U.S.P.N. 5,443,801) in view of Younkes (WO 98/03211) as applied to claims 9 and 15 and further in view of Wright et al (U.S.P.N. 5,639,031) and Koubek (U.S.P.N. 4,512,951).

With respect to claims 12-13, the Langford reference, the Younkes reference and the Wright reference all fail to teach using vaporous hydrogen peroxide; however, the Koubek reference, which is in the art of sterilization, teaches using vaporous hydrogen peroxide (col.3, lines 24-25). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Langford system by substituting one conventional sterilant for another as taught by the Koubek reference since such a substitution results in increasing the killing rate activity of the sterilant by creating a liquid hydrogen peroxide condensate in the presence of a vacuum (col.2, lines 9-15).

With respect to claim 16, the Langford reference uses a pump for moving the sterilant into and out of the container (col.23, lines 44-45), but fails to teach the use of a fan for creating a sterilant motion. The Younkes reference and the Wright reference both fail to teach the use of a fan; however, the Koubek reference, which is in the art of sterilizing medical items by using vaporous hydrogen peroxide, uses a fan (17) for

distributing the sterilant. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Langford system by substituting one conventional moving means for another as taught by the Koubek reference since such a substitution insures a uniform distribution of the inflowing hydrogen peroxide vapors within the container (col.3, lines 63-67).

Response to Arguments

8. Applicant's arguments filed on 07/27/2005 have been fully considered but are found non-convincing.

On page 5 of the Remarks section, applicant argues that, "Applicant submit that such a motivation comes not from the art but rather from Applicant's specification and is therefore improper." The examiner disagrees since the Younkes reference is in the art of designing and maintaining medical containers in sterile conditions so that the contents therein are maintained sterile. The applicant in the instant claims is trying to achieve the same goal. Clearly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Langford system by substituting one closure means for another as taught by the Younkes reference since such a substitution results in the use of partial hermetic seal that insures sterility and allows air to be expelled to the outside (page 13, lines 1-5).

On page 5 of the Remarks section, applicant argues that, "Nothing in Langford nor Younkes, nor in the other cited references, teaches these limitations." The examiner disagrees since the Langford reference teaches a sterilization system that includes a sealed sterilization container (figure 18, 180) for containing items to be sterilized (col.23,

lines 31-32) such that the container has an inlet and an outlet ports (col.23, line 29) and a source of sterilizing fluid attachable to and detachable from the inlet and the outlet ports (col.23, lines 50-52 and lines 59-64).

Conclusion

9. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MONZER R. CHORBAJI** whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 6:30-3:00.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **JOHN KIM** can be reached on (571) 272-1142. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Monzer R. Chorbaji *MRC*
Patent Examiner
AU 1744
10/15/2005

John Kim
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